Attorney Docket No.: 19672-0003US1 / RET/PCG-9009US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kiyotaka Nakano et al. Art Unit: 1643

Patent No.: 7,919,086 Examiner: Lynn Anne Bristol

Issue Date: April 5, 2011 Conf. No.: 4422

Serial No.: 10/583,795 Filed: June 21, 2006

Title : ANTI-GLYPICAN 3 ANTIBODY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 235 days to 325 days is respectfully requested.

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. Patentees respectfully submit that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B).

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

Applicant Delay

A reply to an Office Action was due on or before June 27, 2008 (the date that is three months after March 27, 2008, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on September 29, 2008, thereby according an Applicant Delay of 94 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from June 28, 2008 (the day after the date that is three months after the date on which the Office Action was mailed), to September 29, 2008. See 37 C.F.R. § 1.704(b).

Patentees filed an Information Disclosure Statement on May 14, 2009, subsequent to a reply filed on April 6, 2009. Patentees were accorded a delay of 38 days for a supplemental response. Patentees do not dispute the PTO's calculation for this Applicant Delay from April 7, 2009, to May 14, 2009. See 37 C.F.R. § 1.704(c)(8).

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A reply to an Office Action was due on or before September 26, 2009 (the date that is three months after June 26, 2009, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on December 24, 2009, thereby according an Applicant Delay of 89 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from September 27, 2009 (the day after the date that is three months after the date on which the Office Action was mailed), to December 24, 2009. See 37 C.F.R. § 1.704(b).

Patentees filed an Information Disclosure Statement on December 29, 2009, subsequent to a reply filed on December 24, 2009. Patentees were accorded a delay of <u>5 days</u> for a supplemental response. Patentees do not dispute the PTO's calculation for this Applicant Delay from December 25, 2009, to December 29, 2009. See 37 C.F.R. § 1.704(c)(8).

Patentees filed an Information Disclosure Statement on January 26, 2010, subsequent to a reply filed on December 29, 2009. Patentees were accorded a delay of <u>28 days</u> for a supplemental response. Patentees do not dispute the PTO's calculation for this Applicant Delay from December 30, 2009, to January 26, 2010. See 37 C.F.R. § 1.704(c)(8).

Patentees filed a Petition to Withdraw on August 13, 2010, subsequent to payment of the issue fee. The PTO mailed a response to the Petition to Withdraw on August 16, 2010. Patentees were accorded 0 days delay for deferral of issuance. In good faith and candor, Patentees submit that the deferral of issuance should have been accorded a total Applicant Delay of 4 days for delay from August 13, 2010, to August 16, 2010. See 37 C.F.R. § 1.704(c)(2).

Patentees filed an Information Disclosure Statement on August 20, 2010, subsequent to a reply filed on August 13, 2010. Patentees were accorded 0 days delay for a supplemental response. In good faith and candor, Patentees submit that the supplemental response should have been accorded a total Applicant Delay of 7 days for delay from August 14, 2010, to August 20, 2010. See 37 C.F.R. § 1.704(c)(8).

Patentees filed an Information Disclosure Statement on November 15, 2010, subsequent to a reply filed on August 20, 2010. Patentees were accorded 0 days delay for a supplemental response. In good faith and candor, Patentees submit that the supplemental response should have

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been accorded a total Applicant Delay of <u>87 days</u> for delay from August 21, 2010, to November 15, 2010. See 37 C.F.R. § 1.704(c)(8).

Patentees filed a Response to Notice of Allowance on February 18, 2011, subsequent to the mailing of the Notice of Allowance. The document was coded in the PAIR system as a "Miscellaneous Incoming Letter." Patentees were accorded a delay of 47 days for this post-allowance filing. Patentees respectfully submit that a response to a Notice of Allowance accompanying the payment of the issue fee is not a failure to engage in reasonable efforts to conclude prosecution of the application as intended in 37 C.F.R. § 1.704(c)(10), and requests that the Office recalculate this period of Applicant Delay as 0 days. Id.

As detailed above, 4 days of "A Delay" accumulated during the following period: August 13, 2010, to August 16, 2010.

As detailed above, 7 days of "B Delay" accumulated during the following period: August 14, 2010, to August 20, 2010.

As such, the periods of "A Delay" and "B Delay" overlap (i.e., occur on the same calendar day) for a total of 3 days, from August 14, 2010, to August 16, 2010.

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 349 days (i.e., the sum of 94 days, 38 days, 89 days, 5 days, 28 days, 4 days, 7 days, 87 days, and 0 days, minus 3 days overlapping delay).

"A Delay"

A first PTO action was due on or before August 21, 2007 (the date that is fourteen months after June 21, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on December 18, 2007, thereby according a PTO Delay of 119 days. Patentees do not dispute the PTO's calculation for this "A Delay" from August 22, 2007 (the day after the date that is fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. § 371), to December 18, 2007. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as <u>119 days</u>.

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"B Delay"

There is no dispute that the Office failed to issue a patent within three years of the filing date of the application and that Patentees are entitled to "B Delay" to compensate for that Office delay. The only issue in contention is the correct length of the "B Delay" period.

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP2005/013103, filed July 8, 2005, which claims the benefit of priority of Japanese application number 2004-203637, filed July 9, 2004. The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP2005/013103, filed July 8, 2005. The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(f), i.e., upon express request for processing of the application and upon compliance with all the applicable requirements of 35 U.S.C. § 371(c). As a result, the date that the national stage commenced was June 21, 2006.

The period beginning on June 22, 2009 (the day after the date that is three years after June 21, 2006, the date that the national stage commenced), and ending April 5, 2011 (the date the patent was issued), is 653 days in length. The "PTA 36 Months" entry in the PAIR/PALM system indicates that a total of 417 days were awarded for "B Delay" for this patent. Patentees respectfully submit that the PTO's calculation of this "B Delay" is incorrect.

Section 154(b)(1)(B)(i) of Title 35 excludes from the calculation of B Delay "any time consumed by continued examination of the application." In the present matter, a Request for Continued Examination was filed on August 13, 2010. The Director erred in the calculation of patent term adjustment by subtracting from B Delay a period of time that was not "consumed by continued examination of the application." The PTO mailed a Notice of Allowance on November 19, 2010, thereby closing examination of the application on that date. Thus, no continued examination took place during the 138 day period from November 19, 2010 (the mailing date of the Notice of Allowance), until April 5, 2011 (the date the patent was issued). Accordingly, 138 days of B Delay should have been included in addition to the 417 days accorded by the Director, for a total B Delay of 555 days. Patentees respectfully submit that the

¹ A complete request for early processing under 35 U.S.C. § 371(f) was filed with the present application.

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Office's calculation of "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 555 days.

Overlap of "A Delay" and "B Delay"

As detailed above, 119 days of "A Delay" accumulated during the following period:

August 22, 2007, to December 18, 2007.

As detailed above, 555 days of "B Delay" accumulated during the following periods:

June 22, 2009, to August 13, 2010; and

November 19, 2010, to April 5, 2011.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentees believe the PTA calculation of 235 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 674 days (i.e., the sum of 119 days of "A Delay" and 555 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 349 days; and
- 3) Total PTA should be calculated as 325 days.

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The \$200 fee required under 37 C.F.R. § 1.18(e) is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other credits or charges to Deposit Account No. 06-1050, referencing Attorney Docket No. 19672-0003US1.

Respectfully submitted,

Date: June 6, 2011 /RSMcQuade/

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